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10/628,920

07/29/2003

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EXAMINER

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**BEFORE THE BOARD OF PATENT APPEALS  
AND INTERFERENCES**

Application Number: 10/628,920  
Filing Date: July 29, 2003  
Appellant(s): BOLDUC ET AL.

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Brian S. Tomko  
For Appellant

**EXAMINER'S ANSWER**

This is in response to the appeal brief filed February 4, 2008, appealing from the Office action mailed March 29, 2007.

**(1) Real Party in Interest**

A statement identifying by name the real party in interest is contained in the brief.

**(2) Related Appeals and Interferences**

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

**(3) Status of Claims**

The statement of the status of claims contained in the brief is correct.

**(4) Status of Amendments After Final**

No amendment after final has been filed.

**(5) Summary of Claimed Subject Matter**

The summary of claimed subject matter contained in the brief is correct.

**(6) Grounds of Rejection to be Reviewed on Appeal**

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

**(7) Claims Appendix**

The copy of the appealed claims contained in the Appendix to the brief is correct.

**(8) Evidence Relied Upon**

5,330,503	Yoon	07-1994
4,809,695	Gwathmey et al.	03-1989

**(9) Grounds of Rejection**

The following ground(s) of rejection are applicable to the appealed claims:

Claims 58-69 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gwathmey et al. (U.S. Patent No. 4,809,695) in view of Yoon (U.S. Patent No. 5,330,503). Gwathmey et al. disclose the invention substantially as claimed including a method of forming an anastomosis by placing a lumen of a graft vessel in fluid communication with a lumen of a target vessel through an opening in a wall of the target vessel including the steps of providing a plurality of clips (col. 7, line 15-16) having a first end and a second end (ref. 120, Fig. 4), and each clip having a first configuration (see Fig. 18) and a second configuration (see Fig. 19); passing the first end of each of the plurality of clips through an outer wall of the graft vessel (see Fig. 19; the clips must go through part of the outer wall of the graft vessel in order to form the anastomosis); positioning the first end of the clips through the opening and inner wall of the target vessel (Fig. 18; col. 7, line 32-34; when the surgeon makes the flange, the staple goes through the interior of the target vessel wall); passing at least a portion of the clip through the graft vessel (col. 7, line 34-39); permitting each of the clips to assume a second position to approximate the two vessels (see Fig. 19; col. 7, line 5-61); positioning and spacing the clips radially about the graft vessel (see Fig. 22), each of the plurality of clips being passed through the vessels separately (col. 7, line 1-4; col. 8, line 32-35); compressing the two vessels together when the clip is in the second configuration (see Fig. 19; when the staples are closed, the tissues are further compressed together), the ends of the clip crossing over one another (see Fig. 19; col.

7, line 64-65), each clip isothermally transforming from the first configuration to the second configuration (clips are pushed into the second configuration by the clip applier and jaws), each clip being restrained in the first configuration (col. 6, line 53-59); and releasing the clip from the first configuration with forceps (col. 7, line 57-63; the clip ends are pushed together around the tissue by jaws which allow the mid section of the clip to separate from the connector (ref. 53) in order for the clip to form the second configuration). Gwathmey et al. are silent on the material of the clip but do disclose that the clip must have the capability of being able to be bent into the looped configuration. . A superelastic material is being defined as a material that is capable of changing from one configuration to another when a force that holds the clip in the first position is removed, as disclosed in the present application in par. 81. Yoon discloses that the suturing device contracts after it is inserted into tissue, returning to its pre-suturing shape (col. 8, lines 59-62). Based on the definition being used, the suture material of Yoon is superelastic. Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to have modified Gwathmey et al. with a clip made out of superelastic shape memory material, as taught by Yoon, in order to allow the clip to have the flexibility to be formed into a looped/crossed-over configuration as described in Gwathmey et al. and to have the capability of moving to a second configuration once inserted into tissue and once the insertion device has been removed.

#### **(10) Response to Argument**

Appellant argues that the clips of Gwathmey et al. are not positioned through an opening in a target vessel. As is shown in Fig. 18 and 19 as well as in Fig. 23, the clips

of Gwathmey et al. must go through an opening of each of the vessels in order to secure the vessels relative to one another. Fig. 18 shows two vessel ends (ref. 112 and ref. 114) that each has an interior side. This interior side of the vessels is considered to be part of the opening. As is also depicted in Fig. 20, there is indeed an opening of one vessel that is being secured to the opening of another vessel.

Appellant further argues that the first ends of the plurality of clips of Gwathmey et al. are not passed through an inner wall of a target vessel while the clips are in the first configuration. Appellant recites in the claims that there is a first configuration when first and second ends of the clips are spaced apart from one another. Appellant also recites that there is a second configuration when the portion of the graft vessel and the portion of the target vessel are approximated. As is shown in Fig. 4 of the present application, the two vessels are approximated with respect to one another in the first and second configuration. The two vessels are brought together before the second configuration is reached. Fig. 19 of Gwathmey et al. shows the completed second configuration but before it reaches this configuration, the clip must pass through the inner wall of the vessels which still classifies the clip as being in the first configuration, according to the Appellant's claim limitations.

Appellant also argues that neither Gwathmey nor Yoon disclose a superelastic clip. A superelastic material is being defined, based on the Appellants arguments made in the Appeal Brief filed on February 4, 2008, on page 5, as a material that is capable of changing from one configuration to another when a force that holds the clip in the first position is removed. Yoon discloses that the suturing device contracts after it is

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inserted into tissue, returning to its pre-suturing shape (col. 8, lines 59-62). Based on the definition being used and as supplied by the Appellant, the suture material of Yoon is superelastic.

**(11) Related Proceeding(s) Appendix**

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

/Christina D Gettman/

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